## ClinicalTrials.gov ID: NCT03659032

Efficacy of Pediatric Manual Therapy in the Positional Plagiocephaly

Statistical Analysis Plan

Date: 09/01/2018

## STATISTICAL ANALYSIS PLAN SAP EFFICACY OF PEDIATRIC MANUAL THERAPY IN POSITIONAL PLAGIOCEPHALY

## Statistical analysis

The statistical analysis will be carried out with the software program SPSS v. 22.0 for Mac. Normality of the distribution of quantitative variables will be verified with the Lilliefors-corrected Kolmogorov-Smirnov test. Afterwards, a descriptive analysis of qualitative variables will be performed to obtain absolute and relative frequencies, as well as an analysis of quantitative variables to obtain the mean values ± standard deviation or median values (Q1-Q3), according to whether the distribution of the variables is normal or not, respectively.

Inter-group comparisons between the pre-intervention descriptive and dependent variables and the post-intervention dependent variables will be carried out with nonparametric tests for the qualitative variables (chi-squared test) and the quantitative variables without a normal distribution (Mann-Whitney U test). If the variables have a normal distribution, the inter-group comparisons will be carried out with Student's t-test for independent samples. The effect size of the analyzed interventions will be calculated with Cohen's *d*.

Intra-group comparisons between pre- and post-intervention dependent variables will be carried out with Student's t-test for related samples with a normal distribution. If the distribution of the variables is not normal, the Wilcoxon signed- rank test will be used.

In the parametric analysis, a 95% confidence interval will be used, and a p- value<0.05 will be considered significant.